

### REMARKS

Claims 1 and 5-13 remain in the case. Claims 21- 23 have been canceled. New claims 25-28 have been added and find support at page 7, line 30 to page 8, line 7.

Claims 1, 5, 6 and 8-12 have been rejected under 35 USC 102(b) as anticipated by Padgett (US 4,644,586) or by Trewella et al (US 3,073,507). Applicants disagree.

The claims relate to an article of manufacture formed of a first bag portion that is porous, a second bag portion that is nonporous, a seal formed between the first and second portion of the bag so that the second section is maintained in a sterile condition and the second section is in a condition of either slight vacuum or slight pressure. This structural element of being under pressure or vacuum provides one with a visual indication of integrity.

The Office Action states that the maintenance of the second section under vacuum or pressure sufficient to provide one with a visual indication of integrity is not a structural element of the invention and merely an intended use of the device and therefore does not limit the bag in any structural way. Applicants disagree.

A bag with sealed section under vacuum or pressure sufficient to provide a visual indication of integrity in the second non porous section is a structural limitation of the claimed product itself. Either it has this feature and hence is integral or it doesn't and is not integral. This is not merely an intended use as alleged by the Office Action but is a structural limitation that provides the means for a visual indication of integrity.

As the standard for anticipation is one of strict identity and "the reference must teach every aspect of the claimed invention either explicitly or inherently." (MPEP section 706.02IV, lines 6 and

7) and either cited reference has failed to teach one or more of the claimed elements, neither reference is and cannot be an anticipatory reference. As such, the rejection based on 35 USC 102(b) is respectfully requested to be withdrawn as it fails to provide a reference which contains all of the claimed elements of the present claims and therefore no basis for rejection under 35 USC 102 has been properly made.

Claims 7 and 13 have been rejected under 35 USC 103(a) over Trewella et al in view of McDonald (US 6, 030,578). Applicants disagree.

The claims require that the second section of the bag have a seal formed between the first and section portion of the bag. Further, the second section is either under a slight vacuum or slight pressure to provide one with a visual indication of integrity. A pressure port or a vacuum port are used in the second portion of the bag to do so.

Trewella teaches the use of pressure and vacuum during sterilization but the pressure in the bag is brought back to atmospheric at the end of the sterilization and then the bag is sealed. Thus no pressure or vacuum is used as part of the bag after formation of the seal between the two sections. Moreover it fails to teach or suggest the use of a specific port in the bag for doing so.

McDonald is cited for its collar and that according to the Office Action it would have been obvious to one of skill in the art to use the collar as a pressure or vacuum port. MacDonald, like Trewella prefers to use a panel (11) of gas permeable but microbe impermeable material in its bag and then autoclaves the bag to render its contents sterile. In one embodiment, the entire bag may

be formed of the porous panel material (Column 4, lines 41-44). The panel remains as part of the bag and is not sealed off from a nonporous portion as is claimed in the present invention. Thus the bag of MacDonald remains at atmospheric conditions due to the panel's presence. (Column 4, lines 33-54).

Moreover the teachings of MacDonald are to put the collar into a docking station where the outside of the collar is treated with light to sterilize the outside of the collar that otherwise might be contaminated. The collar is kept in position by an inflatable seal acting on the outer surface of the collar. The Office Action hasn't explained why one would use the collar of the reference as a vacuum or pressure port or why one would want to do so from its teachings.

Lastly, MacDonald as suggested by the Office Action would use a vacuum port or pressure portion the rigid collar, but not on the bag itself as is claimed in the present invention.

One of ordinary skill in the art would not have thought to use the collar of MacDonald to form a vacuum or pressure port in view of the teachings of MacDonald that it prefers to use a gas permeable panel in its bag (and which remains as part of the bag) making such a port irrelevant and useless.

Even in the less preferred embodiments of MacDonald that may use e-beam or other radiation over the "preferred method of achieving sterility" (Column 5, lines 10-11) e.g. autoclaving and hence where there is no necessity for the porous panel, it is silent on the use of vacuum or positive pressure in the bag and fails to teach or suggest any means never mind the formation of a

port to do so. The addition of a vacuum or pressure port would be contradictory and one of ordinary skill in the art would find no teaching, suggestion or motivation in either reference to add such a port. In fact, there are strong indications not to do so in both references in that Trewella has a bag under normal atmospheric pressure and MacDonald prefers to use a porous panel in its bag which likewise is therefore at atmospheric pressure and renders the inclusion of a vacuum or pressure port useless.

The Office Action has failed to provide any explanation as to how and why one of ordinary skill in the art would decide to add such a port in its statements, just merely asserting that the collar could be capable of such a function. **If the Examiner has an explanation, it is respectfully requested that it be provided with citations to the relevant portions of the two references as Applicants are unable to discern any such teaching, suggestion or motivation from the cited combination of references.**

The Patent and Trademark Office (PTO) bears the burden of initially establishing a prima facie case of obviousness. "First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine what the reference teaches. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references combined) must teach or suggest all the claim limitations."

The motivation to make the claimed invention and the reasonable expectation of success must both be found in the prior art, not the applicant's disclosure. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). The references must be considered as a whole and must suggest

the desirability, and thus the obviousness of making the combination. *Hodosh v. Block Drug Co., Inc.*, 229 U.S.P.Q. 182, 187 n.5 (Fed. Cir. 1986); MPEP § 2141.

Neither reference teaches, hints or suggests a bag that has a sealed nonporous section containing sterile elements that is either under a slight vacuum or a slight positive pressure. Moreover, neither alone or together suggest the use of port on the bag to place that portion of the bag under pressure or vacuum so as to provide a visual indication of integrity. In fact as discussed above, the preferred inventions of the references have their bags under normal atmospheric conditions. MacDonald goes even further in preferring to keep the porous panel as part of its bag.

Under 35 U.S.C. 103(a), there must be some objective teaching, suggestion or motivation in the prior art that would have motivated one of ordinary skill in the art at the time the invention was made to arrive at the claimed invention as a whole. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case there is none. The Office Action simply contends that MacDonald could be capable of doing so and that it would have been obvious to do so to the bag of Trewella while ignoring the clear teachings of both. Applicants contend that the finding of obviousness was based on knowledge gleaned only from Applicant's own disclosure, and that this rejection is therefore based on improper hindsight reasoning. Applicants acknowledge that while "[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). [emphasis added] and that the risk of hindsight bias should not be overemphasized so as to defy common sense (*KSR International Co.*

Appln Serial No. 10/659,570  
Amdt of September 17, 2008  
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Page 10

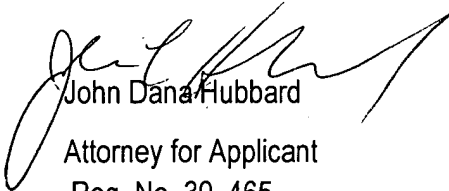
*v. Teleflex Inc.*, 82 USPQ2d 1385, 1397 (2007), but here that emphasis is not logical and clear and appropriate given the teachings of the combined references.

As such, the prima facie case of obviousness has not been established and the rejection should be withdrawn.

New claims 25-28 are also not anticipated nor rendered obvious from the cited reason for the reasons stated above in regard to the existing claims. Moreover, the references fail to teach or suggest connecting the port to an integrity test or applying an integrity test to the bag after its formation.

Reconsideration and allowance of the claims is respectfully requested.

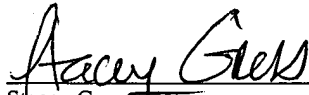
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